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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,634	03/23/2004	Manuel Fresno Escudero	A34909-PCT-USA-I 069277.0	2456
21003	7590	11/09/2005	EXAMINER PAK, YONG D	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,634

Applicant(s)

FRESNO ESCUDERO ET AL.

Examiner

Yong D. Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a divisional of 10/031,047, which is a 371 of PCT/ES00/00245.

The amendment filed on July 29, 2005, amending claims 9 and 11-12, has been entered.

Claims 9-12 are pending and are under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 and claims 10-12 depending therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recite the phrases "under conditions that allow the transcription of the cyclooxygenase 2 promoter to be active". It is not clear to the Examiner as to what "conditions are encompasses in the above phrase. A perusal of the specification did not provide the Examiner with a specific definition for the above phrase. Therefore, it is not clear as to what are those conditions in which COX-2 undergoes transcription.

Examiner requests clarification of the above phrase. Furthermore, it is also not clear to the Examiner as to what applicants mean by the phrase "to be active" in the above phrase. It appears that applicants mean "transcribe" or "express". If that is so,

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Examiner suggest substituting the more appropriate term "to transcribe", for example, in place of "be active".

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "wherein the stimulator" in line 12. There is insufficient antecedent basis for this limitation in the claim. Claim 9, from which claim 12 is dependent from, does not recite a "stimulator".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kutchera et al., Dannenberg et al. and Iniguez et al.

Claims 9-12 are drawn to a method of identifying compounds that inhibit the induction of human cyclooxygenase-2 gene transcription by contacting a Jurkat cell comprising 1.9 kb of a human COX-2 promoter linked to a luciferase gene with a test compound in the presence of PMA.

Kutchera et al. (cited previously on form PTO-892) teach a 1.9 kb of a human COX-2 promoter linked to a luciferase gene (abstract, page 4817, left column and page 4818, right column). Kutchera et al. also teach that the luciferase gene linked to the promoter region of human COX-2 can be used to examine transcription levels of the COX gene (page 4818, right column).

The difference between the reference of Kutchera et al. and the instant invention is that the reference of Kutchera et al. does not specifically teach the use of said construct in a Jurkat cell for identifying compounds that inhibit the induction of human COX-2 in Jurkat cells, even though it suggests the use of such a construct for examining of transcription of COX-2.

Dannenberg et al. (WO 98/37235 or U.S. Patent No. 6,200,760 – form PTO-1449) teach a method of identifying compounds that inhibit the induction of human

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cyclooxygenase-2 gene by contacting a cell comprising a human COX-2 promoter linked to a luciferase gene with a test compound in the presence of a PMA and an ion and measuring luciferase activity in the presence and absence of test compounds (pages 6-10, 14-17 and 23-25 or (abstract, Columns 2-8 and claims 1-2). However, the human COX-2 promoter of Dannenberg is 1.4 kb.

Iniguez et al. (form PTO-892 - J Immunol. **1999 Jul 1**;163(1):111-9) discloses the use of Jurkat cells for a method for identifying compounds that inhibit induction of a gene using reporter gene assays (pages 112 and 115-116). Iniguez et al. teaches expression/induction of COX-2 promoter in Jurkat cells and also teaches that identification of compounds that inhibit COX-2 induction in Jurkat cells are important in identifying immunosuppressive drugs (abstract and page 112). However, the reference does not specifically teach the use of constructs comprising COX-2 promoter linked to reporter genes.

With the teaches of all the reference in hand, it would have been obvious to one skilled in the art to combine the teachings of Kutchera et al., Dannenberg et al. and Iniguez et al., to interchange the polynucleotide construct of Dannenberg et al. with the polynucleotide construct of Kutchera et al. in practicing the method of Dannenberg et al. and using Jurkat cells as taught by Iniguez et al. One of ordinary skill in the art would have been motivated to combine the references in order to rapidly screen for inhibitors of COX-2 in Jurkat cells using the shorter fragment of Dannenberg et al. or the longer promoter fragment of Kutchera et al., specifically to identify compound with affect transcription of COX-2 as opposed to modulating the activity of COX-2 protein and also

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due to the potential of binding more test compounds, thereby resulting in a more comprehensive assay of screening for transcriptional inhibitors of COX-2 useful as immunosuppressive drugs. One of ordinary skill in the art would have had a reasonable expectation of success since Kutchera et al. teaches that the luciferase gene linked to the COX-2 promoter can be used to monitor transcription levels of COX-2, Dannenberg et al. successfully teaches a method of identifying compounds that inhibit induction of COX-2 by measuring luciferase activity, wherein the luciferase gene is ligated to a promoter of human COX-2 and Iniguez et al. successfully teaches the inherent expression of human COX-2 in Jurkat cells and a method of measuring transcriptional activity of a gene using a reporter gene in Jurkat cells.

Therefore, the above references render claims 9-12 *prima facie* obvious to one of ordinary skill in the art.

In response to the previous Office Action, applicants have traversed the above rejection.

Applicants argue that claims 9-12, as amended, are not obvious over Kutcher et al. or Dannenberg et al. because the references fail to teach or suggest using Jurkat cells and activity of a gene construct is not easily predictable from one cell line to another. The rejection has been amended to address this new limitation. Newly cited reference, Iniguez et al., teaches the inherent expression/induction of COX-2 promoter in Jurkat cells and teaches a method for identifying compounds that inhibit induction of a promoter in Jurkat cells using reporter gene assays (pages 112 and 115-116) as well. Iniguez et al. also teaches that identification of compounds that inhibit COX-2 induction

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in Jurkat cells are important in identifying immunosuppressive drugs (abstract and page 112). Therefore, combining the teachings of Kutchera et al., Dannenberg et al. and Iniguez et al., it would have been obvious to one having ordinary skill in the art to interchange the polynucleotide construct of Dannenberg et al. with the polynucleotide construct of Kutchera et al. in practicing the method of Dannenberg et al. and using Jurkat cells as taught by Iniguez et al.

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

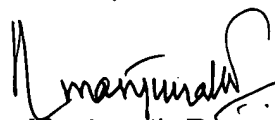
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner 1652

A handwritten signature in black ink, appearing to read 'Manjunath Rao', with a stylized flourish at the end.

Manjunath Rao
Primary Patent Examiner 1652